Notes To The File

Summary of Outreach Meeting to Mexico on the Bioterrorism Act: Registration of Food Facilities and Prior Notice of Imported Food Shipments Proposed Rules
February 6, 2003
Mexico City, Mexico

(These notes are not intended as a verbatim transcript of the meeting, but a summary of the key points discussed.)

FDA Participants:
Camille Brewer, International Activities Coordinator, Center for Food Safety and Applied Nutrition (CFSAN)
Leslye Fraser, Associate Director for Regulations, CFSAN
Bob Lake, Director, Office of Regulations and Policy, CFSAN
Steve Niedelman, Assistant Commissioner for Regulatory Affairs, Office of Regulatory Affairs
Melinda Plaisier, Assistant Commissioner for International Programs, Office of the Commissioner

Session One:
Mexican Government Participants: Representatives from SSA/COFEPRIS, SENSICA/SARGARPA, CNIAA, FUMEC, Queretaro, DGN/SE, DGN/Economia [and trade lawyers]

Others: Kraft, IICA, U.S. Embassy

Registration

- Will registration be denied to anyone?
  - *No, registration is just that – there is no evaluation – other than providing the necessary requested information*

- If the Mexican product is sold to a trader, who has to register?
  - *The registration is by the facility. The facility has to register unless another foreign facility further processes or packages the food before it is exported to the U.S.*

- We ask for a telephone number and email address. In many areas of Mexico, that is impossible. Not everyone has a telephone or access to email.
  - *Farms are exempt, but the entity required to register is not required to have a telephone number and email address. We are just requesting that information if it is available.*

- What about food that is sent to the U.S. for reprocessing?

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- *The facility sending the food to the U.S. for reprocessing would have to register, unless they are subject to an exemption (e.g., the facility is a farm.*

- Are live animals for consumption subject to this regulation?
  - *No. The registration requirement applies to facilities, not to specific food products. Facilities that manufacture/process, pack or hold live food subject to FDA's jurisdiction would have to register, unless they are exempted from the rule.*

- Will they have an opportunity to comment on other possible modifications? Not just including these provisions? We really need to discuss these, and need time.
  - *The President has signed the bill into law, and FDA is under statutory deadlines to implement these provisions. Today's session is one opportunity for us to hear your concerns, comments, and questions, and we urge you to submit written comments into the docket by April 4, 2003. Due to the statutory timeframes we must meet, we will not be able to extend the deadline for comments.*

- FDA is requiring companies to register, what if there is a conflict with Mexican law?
  - *This requirement has only to do with exporting food for human or animal consumption into the U.S. It has no bearing on Mexican laws and regulations. This is U.S. law that must be met in order to export food commodities into the U.S. for consumption in the U.S.*

- How will we check the truth of the data? False data – what will we do to prevent false data from being supplied? How can we ensure security of the internet registration system so that once a company registers, someone else can't access their files.
  - *Over time, the system will provide a set of checks and balances. Part of the system for registration is a requirement that FDA hold the information confidential. We are prohibited by statute from disclosing the information to the public. We urge you to also hold your registration number confidential so it can not be accessed or used by someone else. The agency has a long history of managing confidential or protected information and has had very few problems. The electronic registration will require a password or some other security measure so that only the company registering will be able to access their registration.*

- U.S. Agents – how will that be updated?
  - *As a facility changes who is their U.S. agent, the proposed rule would require the facility to provide that information to FDA within 30 days of the change.*

Prior Notice

- This provision is the most important for Mexico because of the volume of food trade Mexico does with the U.S. This represents a real disadvantage for food exports. Many farmers/manufacturers/shippers are less than 10 hours away from the border – loading/off-loading systems don't have refrigeration to keep perishable goods. They need our support for an exemption. 12 hours is too much time.
    - *We heard similar comments in Canada and we welcome your comments on the timing issue. Keep in mind that this provision is intended to allow FDA sufficient time to make preliminary decisions about what imported food shipments we need to inspect, and assure we can have an FDA inspector at a port-of-entry, when needed.*

- Notification procedures – what do we mean by "arrival at the border"? When Customs receives notice or when the shipment physically arrives at the border? The time is very different.
    - *Arrival at the border means physically arriving at the border to enter the U.S.*

- Time – hour of notification. What time zone are we using? EST (WDC) or time at the border?
    - *The time zone of the port-of-entry is the appropriate time zone.*

- Time of inspection – what will the type inspections will we be doing the border? How will they change?
    - *We do not anticipate the volume of inspections or the type of inspections to change significantly. We will continue to use the procedures we currently use. The only difference is that we will have advance notice of incoming shipments that will enable us to better plan what products we wish to examine.*

- Registration of the facility – what happens after December 12? Companies are created all the time?
    - *December 12, 2003 is the date the provision becomes effective. All currently existing facilities that manufacture/process, pack or hold food for consumption in the U.S. must be registered with FDA by December 12, 2003 if they want to continue to export to the U.S. New companies that are created after December 12, 2003 will simply need to register before they may begin exporting to the U.S.*

- What happens at the border if prior notice confirmation was not received?
    - *The food will be held at the port of the entry (unless FDA directs its removal to a secure facility) until FDA receives adequate prior notice.*

- If anyone puts the registration number on the label, then there is a mistake, would they have to register again?
    - *No. We discourage firms from placing their registration number on the labels. It is in the firm's best interest to keep that information as private as possible to reduce the risk of use of their number by others – thereby increasing "gray market" products on the market. In addition, companies should not give the impression that being registered with FDA means FDA endorses the product.*

- Very big burden – a huge trade barrier
- (Ministry of Economy) Also concerned about the impact product access to the U.S. might have on their economy, and the trade issue. Exactly how can we demonstrate that this is compliant with WTO and NAFTA, and not creating trade barriers?
    - *Our President, who is also deeply committed to free trade, signed this bill into law. FDA fully intends assure that these regulations meet our obligations under the WTO and NAFTA, and are as least trade restrictive as possible. Further, we will have a publicly available WTO risk assessment on the entire statute, not just these provisions by the time we publish the final rules.*

- What is our justification to impose such stringent measures?
    - *Much of the scope of these provisions is in the statute. We did, as required by law, conduct an economic impact assessment and are open to comments on how to reduce burden while meeting our obligations under the statute..*

Session Two:

Mexican Industry Participants: Approximately 100 participants representing the following industries: Multinational food manufacturers, juice, packing, labeling, spirits, fresh fruits and vegetables, meat, fats and oils, renders, agriculture development.

Registration

- Is it an option to have a U.S. Agent? Is the Agent only for registration? Can they pick the Agent?
    - *No, must have a U.S. Agent if you want to do business with the U.S. The Bioterrorism Act requires every foreign facility that manufactures, processes, packs or holds food for human or animal consumption in the U.S. to have a U.S. agent. The proposed rule would require the U.S. agent to reside or maintain a place of business in the U.S.*

    - *Yes, you can pick the Agent. It is the facility that chooses who will serve as their U.S. agent.*

- How much will it cost to have a U.S. Agent?

- *Based on the drug registration that has been in effect for some time, we estimate it will cost about $1200 per year. It is part of the economic impact analysis on which we seek comment.*

- Tequila exports: all are packed in bulk, and then held in tankers that ship to the U.S. Do they have to register the tankers?
  - *If the tanker is holding, pending transport then the tankers would not have to register. If the tankers are parked and used primarily for storage, then yes, they would have to register.*

- Could one Agent represent all of the exporters? Could they all use the Mexican representative in Washington, D.C.?
  - *Yes.*

- Very concerned that these provisions are a consequence of terrorism.
- Does registration mean further certification from FDA?
  - *No, registration is not an evaluation.*

- A businessperson buys canned foods made by another manufacturer. Who has to register?
  - *The manufacturer needs to register. But, the businessperson should assure that the manufacturer has registered, so the products can be imported into the U.S. The Bioterrorism Act requires food from an unregistered facility to be held at the port of entry.*

- There are many small family-owned businesses, with 1 or 2 employees. Will they have to register? Any way to exempt them?
  - *Yes, they will have to register. We would welcome comments on this, but the proposed rule contains no exemptions for small businesses either in the U.S. or in other countries.*

- Do makers of raw materials have to register?
  - *Yes, if the raw materials are being shipped to the U.S. for further processing as food. If the raw materials were being sold within Mexico, further processed, then exported, the manufacturer/processor of the raw materials intended for food would have to register.*

- What is the purpose of having a U.S Agent?
  - *It is mirrored off the medical device and drug registration provisions in our statute, and the general concept is that if you are doing business in the U.S., you should have a U.S. contact should any problems arise.*

- What is the period of registration?
  - *Unlimited. Once the provision goes into effect December 12, registration will be required for all facilities that manufacture/process, pack or hold food for consumption in the U.S.*

- Warehouses that hold products for distribution. Do they have to register?
  - *Yes.*

- What kind of security will we have to protect the Internet?
  - *FDA has a long history of successfully managing confidential information. For registration, there will be safeguards built into the system, such as needing a passwork to access your registration.*

- Compliance with registration – or lack of prior notice. We said it is a prohibited act, and subject to criminal prosecution or administrative action. How will we decide to pursue criminal actions?
  - *As you know, the U.S. has no authority to exercise law enforcement outside the U.S. The criminal sanctions are for violations within the U.S. The penalty for foreign entities for non-compliance will be that the products will not be allowed to enter the U.S. There is another provision in the statute - debarment – that will allow us to debar a person who has a history of violations relating to the importation of food into theU.S..*

- Tequila producers – the tequila comes from agave – lots of farmers. But the product (the spirits) are manufactured in Mexico, then sent to the U.S. Do the agave growers have to register?
  - *No, farms are exempt. The manufacturer of the spirits (bulk or bottled) that are exported has to register.*

- What about bulk commodities – do they have to register?
  - *Yes.*

- When you update a registration, do you get a new registration number?
  - *No.*

<u>Prior Notice</u>

- There is a large gray market. What can we offer them as protections?
  - *If we become aware of instances of fraud, we will take action and notify the company. As these systems and our experience mature we will be able to better detect gray market products by comparing products listed in prior notices with products identified in firm registrations. That just stresses the importance of maintaining up to date registrations.*

- Grains and oils. Do they have to give prior notice?
  - *Yes, if they want to enter the U.S., because these are foods regulated by FDA.*

- Concerned about ingredients/raw materials. The materials are standardized in the U.S by a sister company. The U.S. company then sells to the U.S. market. Do they need to register?
    - *Yes, as ingredients and raw materials intended to be used as food are types of food regulated by FDA.*

- Plants are in one state and Headquarters in another. Who has to register?
    - *If HQ facility also manufactures/processes, packs, or holds food for consumption in the U.S., then both facilities would have to register. If the HQ facility is only administrative, then only the plant would have to register. Every facility that manufactures/processes, packs, or holds food for consumption in the U.S. has to register. Facilities that do not engage in these activities do not.*

- Containers and packaging suppliers. Do they also have to register?
    - *If the containers or packaging materials are shipped to the U.S. to be filled in the U.S. then the company must register. If the containers or packaging materials are sold within Mexico, filled in Mexico, then the filled containers are exported, then only the manufacturer who filled the containers must register.*

- What about food samples that are sent to the U.S.? They are not sent for commercial sale or further processing, they are sent for marketing purposes to see if U.S. companies want to buy?
    - *As written, yes, you would be subject to this regulation, but we would welcome your comments on this.*

- Really concerned about trade implications. We're also really concerned about the safety of our citizens. Our President's have a very close relationship, this will violate NAFTA – how can we explain?. What would we say if Mexico wanted to create mirror legislation?
    - *We share your concern about the safety of your citizens. While this bill is specifically intended to give additional tools to protect American citizens, we do care about our southern and northern neighbors. We discussed this issue in Canada. Hopefully we will never have a situation where we need to exercise enforcement over a possible terrorist threat to our food supply, but if we do, we need to discuss what systems we can put in place to share the information with all other foreign countries that could be potentially affected. We are committed to the safety and security of the food supply. We are also committed to meeting our obligations under the WTO and NAFTA. With respect to the question about mirror legislation, we would never presume to advise Mexico about your legislative needs.*

- What if we hold a product because we receive information from the FBI that there is a possible threat. The product is sampled and it's determined to be ok, but by

then, the product is spoiled. Who pays for the loss of the products? Will the U.S. government?
    - *The loss would be borne by the importer. There is no provision for the U.S. government to cover any losses.*

- Are we working with Customs on this? They already have to comply with Customs requirements. Do they now have to do both?
    - *Yes, we are working closely with Customs, and we hope to have compatible computer systems by 2005. Yes, you do have to comply with both Customs and FDA requirements.*

- What about an imported finished product made in the U.S. It is sent to Mexico, where they add seasoning, etc. They send promotional materials and they are in Spanish. These requirements must be in English. Will they now be violating something?
    - *These proposed rules have nothing to do with direct-to-consumer advertising, labeling, or promotional materials.*

- How are truckers/shippers supposed to manage. So many factors impact delivery – accidents, robbery, weather, change of routes.
    - *We heard similar comments in Canada, and welcome your comments on the practicalities.*

- Does FDA have the proper infrastructure to be able to process 20,000 per day?
    - *Yes, we fully expect to be ready to receive and manage this information by the date of enactment.*

- What happens if the notification system crashes?
    - *In that instance, and that instance only, the notification can be hand-carried, faxed, or emailed to the FDA office responsible for that port of entry. Information about where those offices are, and contact information will be posted on the web.*

Submitted by: Melinda Plaisier, Feb. 27, 2003